

North Carolina Health Information Exchange Governance Work Group
Recommended Criteria and Process for Establishing Qualified Organizations
May 17, 2011

1. Introduction

The North Carolina Health Information Exchange (NC HIE) is a not-for-profit, public-private partnership that has been designated by the Governor of North Carolina and by the federal Office of the National Coordinator for Health Information Technology as the official state designated entity responsible for coordinating and executing a strategy for enabling statewide health information exchange in North Carolina.

NC HIE's vision is to provide a secure, sustainable technology infrastructure that supports the real time exchange of health information throughout North Carolina to enhance medical decision-making and the coordination of care, increase system efficiencies and control costs, and improve health care quality and health outcomes for all residents of the state.

NC HIE intends to realize this vision by (1) supporting an open and transparent, statewide, collaborative process to develop Statewide Policy Guidance (i.e., the "rules of the road") for the statewide HIE network, and (2) providing the core technology services and select "value-added" services that are made accessible via the Statewide HIE Network.

NC HIE has adopted a Qualified Organization (QO) approach to manage participation in the statewide network. Essentially designed to be a "system of systems."

A QO's most basic function is to serve as an organizer or aggregator of providers for the purposes of connecting them into the statewide network. To ensure the security and operational integrity of the Statewide HIE Network, authorized healthcare professionals will access data and services through QOs.

While participation in the statewide HIE will be voluntary, a QO must sign a participation agreement which will bind the QO and its participants to compliance with the Statewide Policy Guidance developed by the NC HIE through its collaborative process.

In order to ensure that a QO is capable of fulfilling the technical and policy requirements associated with participation in the Statewide HIE Network and specified in the participation agreement, NC HIE has created an application and selection process, described herein, through which an entity must demonstrate its ability and willingness to meet selection criteria before being designated by the NC HIE as a QO and receiving subsequent access to the Statewide HIE Network.

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2. Key Definitions

The Qualified Organization framework involves the interrelationship of a number of important entities and policies. The roles and responsibilities of each of these entities with regard to the Statewide HIE Network are defined below.

NC HIE

The not-for-profit, public-private partnership designated by the state to coordinate and execute a strategy for enabling statewide health information exchange in North Carolina. NC HIE is the entity that is responsible for, among other things, supporting the statewide collaborative process to develop Statewide Policy Guidance and contracting to provide the core technology services and select “value-added” services that are made accessible via the statewide network.

NC HIE Statewide Policy Guidance

Statewide Policy Guidance (SPG), to be developed by the NC HIE through the Work Group process and with Board approval, will provide a common and consistent technical, privacy, security, and legal framework for participants in the HIE and ensures the secure, interoperable exchange of data through the statewide network. SPG will include:

1. detailed rules for privacy and security, technical interoperability and financial obligations;
2. vendor contract requirements;
3. ongoing governance structure and participation requirements; and
4. enforcement mechanisms.

Qualified Organizations

QOs are entities that meet an established set of criteria (detailed in the section that follows) and have gone through an approval process to be deemed QOs.

By virtue of being designated a qualified organization and entering into contractual agreements with the NC HIE which legally bind them to the SPG, QOs will have permission to access, consume and make available health information and HIE services on the Statewide HIE Network.

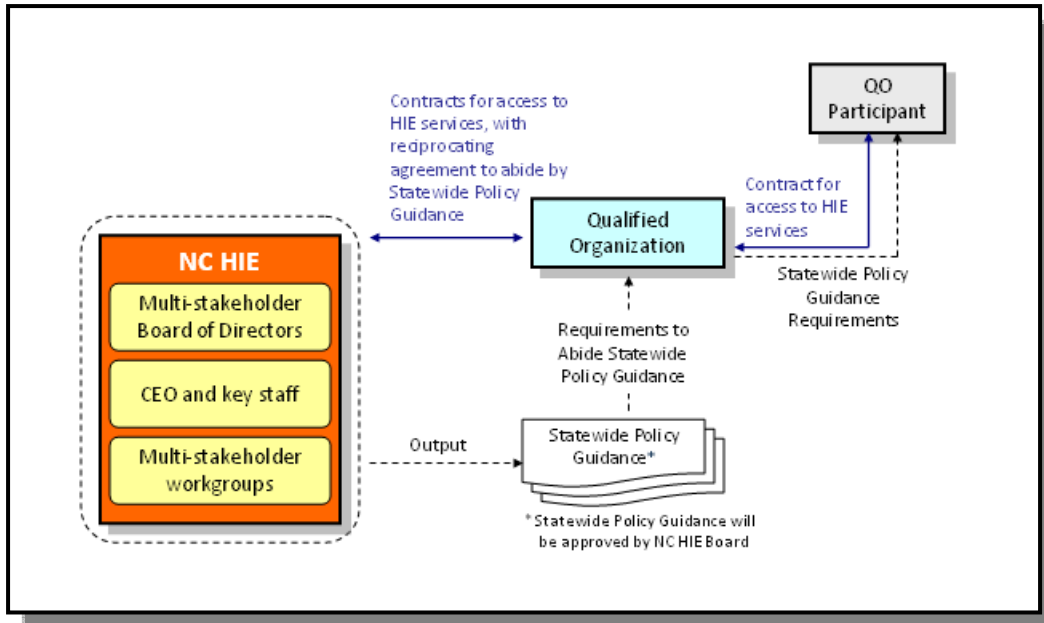
Through these signed agreements, QOs will be required to ensure that participants and vendors with which they have contracts also meet requirements and comply with the SPG.

Qualified Organization Participant

Qualified Organization Participant or QO Participant means a provider or entity that participates in the Statewide HIE Network through a Qualified Organization.

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Below is an illustration of the relationship between participants in NC HIE's Statewide HIE Network.



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3. Qualified Organization Selection Criteria

The NC HIE Governance Work Group recommends that entities seeking QO status:

1. Be organized as a non-profit or for-profit corporation whose articles of incorporation have been filed with the North Carolina Department of the Secretary of State (or that has a certificate of good standing if incorporated in a state other than North Carolina).
2. Agree to comply with NC HIE's Statewide Policy Guidance (including technical specification and privacy and security requirements) and ensure that QO participants comply with them.
3. Agree to comply with, and ensure that its participants comply with, NC HIE's Fair Information Policy Principles described in Exhibit A below.
4. Provide to NC HIE a list of current participants, updated on a regular basis in compliance with a process to be established by the NC HIE Board, and a plan for adding more participants.
5. Submit and annually update a Program Plan that describes specific activities in which the QO will engage, including:
 - Marketing the HIE and recruiting participants
 - Enrolling and billing participants for QO and HIE services
 - Collecting and maintaining agreements with their QO participants
 - Maintaining a customer support process to field participant questions
 - Creating and maintaining a fair grievance process
 - Allocating resources for participation in statewide HIE collaborative process
 - Overseeing, auditing, and reporting QO participants' compliance with the Statewide Policy Guidance and any other applicable requirements
6. Demonstrate financial viability:
 - (a): On an annual basis:
 - Submit a detailed business plan, including a three-year projection of expenses and income and other sources of future revenues.
 - Submit a rate plan outlining fee structures for HIE service for participants in the QO.
 - Submit results of annual independent financial audit.
 - (b) Demonstrate adequate liability coverage relevant to the exchange of individually identifiable health information (e.g., directors' and officers' liability, data theft, data mismanagement, data generation errors, data breach, etc.), in accordance with such standards as may be required by the NC HIE board of directors.

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4. Qualified Organization Application Process

NC HIE staff will design and develop the process for receiving, reviewing, and rendering decisions for entities' applications to be designated as Qualified Organizations.

5. Renewal of Qualified Organization Status

Qualified Organizations will be required to annual update a Program Plan (as detailed above) and to comply with NC HIE policies and procedures. Provided a QO complies and is in good standing, the QO's status in the HIE will automatically continue on an annual basis without a formal renewal basis.

Should concerns be raised by NC HIE leadership about non-compliance, the QO will be required to submit an action plan and timeline to remediate the issues and the plan must be approved by NC HIE.

6. Repercussions for Non-Compliance with NC HIE Policies and Procedures

Repercussions for non-compliance with NC HIE's policies and procedures will be defined in NC HIE's contracts and participation agreements with QOs.

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Exhibit A: North Carolina Fair Information Policy Principles

- **Individual Access and Control**: Individuals should be provided with a simple and timely means to access and obtain their individually identifiable health information in a readable format and form. Further, there should be openness and transparency about policies, procedures and technologies that directly affect individuals and/or their individually identifiable health information, including their ability to opt-out or otherwise limit disclosure.
- **Collection, Use and Disclosure Limitation**: Individually identifiable health information should be collected, used and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately.
- **Data Quality and Integrity**: Persons and entities should take reasonable steps to ensure that individually identifiable health information is complete, accurate and up-to-date to the extent necessary for the person's or entity's intended purposes and has not been altered or destroyed in an unauthorized manner. Further, individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information, and to have erroneous information corrected or to have a dispute documented if their request are denied.
- **Safeguards**: Individually identifiable health information should be protected with reasonable administrative, technical and physical safeguards to ensure its confidentiality, integrity and availability and to prevent unauthorized or inappropriate access, use or disclosure.
- **Commitment to Reciprocity and Timeliness**: Participants in the HIE should exchange individually identifiable health information freely with other providers and organizations that have been formally approved to participate in the HIE to coordinate patient care in accordance to the manner, timeframe, technical standards and implementation specifications defined in North Carolina's Statewide Policy Guidance.
- **Accountability**: These principles should be implemented, and adherence assured, through appropriate monitoring and other means and methods should be in place to report and mitigate non-adherence and breaches.